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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,772	07/12/2001	Masahiro Iwamoto	46124-5001-01	1361

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/902,772	IWAMOTO ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *March 23, 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *32 and 34*.

Claim(s) withdrawn from consideration: *1,5,20-31,33,35 and 39*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *See Continuation Sheet*

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EX.
TECHNOLOGY CENTER 1L

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Continuation of 3. Applicant's reply has overcome the following rejection(s): The amendment overcomes the rejection of Claim 34 as being anticipated by Dhordain et al. because Dhordain et al. does not disclose a C-11 gene .

Continuation of 5. does NOT place the application in condition for allowance because: Claim 32 remains unpatentable over Dhordain et al. Applicants argument that the amendment inserting that the composition is "suitable for injection or oral administration" distinguishes the claimed composition over the prior art because the Lipofectamine contained in the prior art composition would not be suitable for in vivo use is not persuasive. Applicants have not provided evidence that Lipofectamine cannot be used in vivo and Toyoda et al. (cited herein) provides evidence that Lipofectamine can be used in vivo. Moreover, the composition taught in Dhordain et al. includes the c-erg containing composition prior to the addition of LIpofectamine. Applicant has not distinguished the claimed composition over that of Dhordain et al. The present Application differs from the reference case law because the present claims do not require combination with a pharmaceutically acceptable vehicle (Ex parte Clark), the Dhordain et al. composition does not contain anything that would not allow its in vivo use (Ex parte Cole), and the present issue is one of anticipation (are the products patentably distinguishable) and not obviousness (did the prior art suggest the product). The rejection of Claims 32 and 34 under 112, 1st paragraph is maintained. Applicants have not addressed the examiner's evidence that those of skill in the art consider gene delivery to be extremely unpredictable, highly unsuccessful and dependent on each individual gene (see Verma et al., Anderson et al., Romano et al., Somia and Verma, and also Nishikawa et al. (the latter who indicate that gene delivery is not routine and is dependent on the DNA-vector complex). As stated in the previous Office Action, it appears that while Applicants in vitro model may represent the activity of the erg or C-11 genes in vivo in their natural state (as indicated by the abstracts cited by Applicant), the model and Specification do not provide sufficient information that would have allowed one of skill in the art to use the claimed pharmaceutical compositions in a method of gene therapy. The examiner also clarifies that the '859 patent differs from the present situation in that it provides detailed examples of injection of the DNA whereas the present Application merely implies that DNA delivery is desired and does not provide any guidance with regard to how the DNA would be delivered. Moreove the '859 patent does not address ora delivery of DNA. As stated in Genentech v. Novo Nordisk A/S 42 USPQ2d 1001, "when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." (Genentech v. Novo Nordisk A/S 42 USPQ2d 1001, 1005). The intended use o the presently claimed products in methods of treatment only provides a starting point for further research. As stated previously, removal o "pharmaceutical" from Claim 34 and cancellation of Claim 32 would overcome the rejections.

Continuation of 10. Other: see attached Form 892--citation of reference necessiated by amendment..